	ectly with the competent Interna	ational Preliminary Examini.	thority or, if two or more Authorities are competent,
	applicant. The full name or two-	letter code of that Authority may	be indicated by the applicant on the line below:
TPRA/US		, and a second second	or translated by the applicable on the line below:

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

Fo	r International Preliminar	y Examining Authorit	y use only		
Identification of IPEA		Date of receipt of DEMAND			
Box No. I IDENTIFICATION OF THE INTERNATIONAL		APPLICATION	Applicant's or agent's file reference 32483-05		
International application No. PCT/US2004/38044 International filing date 15 NOVEMBER 20			(Earliest) Priority date (day/month/year) 13 NOVEMBER 2003 (13.11.2003)		
	Title of invention IMAGE MANAGEMENT SYSTEM FOR USE IN DERMATOLOGICAL EXAMINATIONS				
Box No. II APPLICANT(S)					
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) DIGITALDERM, INC.			Telephone No. 803.231.2002 Facsimile No.		
1334 Sumter Street			803.978.7456		
Columbia, South Carolina 29	201		Teleprinter No.		
Officed States of Afficia	United States of America				
State (that is, country) of nationality: US State (that is, country) of residence US			y) of residence:		
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) KUDRA, Malcolm J. 4531 Lynnay Drive Rembert, South Carolina 29128 United States of America					
State (that is, country) of nationality: US State (that is, country) of residence: US					
Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.) GRICHNIK, James 103 Toynbee Place Chapel Hill, North Carolina 27514 United States of America					
State (that is, country) of nationality: US		State (that is, country) US	of residence:		
Further applicants are indicated on a continuation sheet.					
Form DCT/IDE A /401 (Feet about / 4 - 11 000					

Form PCT/IPEA/401 (first sheet) (April 2006)

C EQ272414665US

Thereby certify that this paper or the whole the demand form deposited with the U.S. Postal Service
"Express Mail" Post Office to Addressee"
service under 37 CFR 1.10 on the date indicated below and addressed to the Director of the United Selection Ratent & Trademark Offic: 1431;

Alexandria Vitalian Cold

Sheet No. $\,\cdot\,2$

International application No. PCT/US2004/38044

Continuation of Box No. II APPLICANT(S)	1.01/00200-1/000-14			
If none of the following sub-boxes is used, this sheet should not be included in the should not be s	ded in the demand			
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CHESNUTT, Samuel T.	just officials designation. The discress must include postal code and name of country.)			
6130 Hampton Ridge Road				
Columbia, South Carolina 29209				
United States of America				
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Further applicants are indicated on another continuation sheet.				

Sheet No. . .3

International application No. PCT/US2004/38044

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE				
The following person is agent common representative				
and K has been appointed earlier and represents the applicant(s) also for international p	reliminary evemination			
is hereby appointed and any earlier appointment of (an) agent(s)/common represe				
is hereby appointed, specifically for the procedure before the International Prelim				
the agent(s) continion representative appointed earner	unally Examining Authority, in addition to			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	Telephone No. 864.370.2211			
John B. Hardaway, III; Michael A. Mann;	Facsimile No.			
J. Herbert O'Toole, Joseph T. Guy	864.282.1177			
NEXSEN PRUET ADAMS KLEEMEIER LLC	Teleprinter No.			
P.O. Box 10107	receptificative.			
Greenville, South Carolina 29603	Agent's registration No. with the Office			
United States of America	A Sour Stogistiation INO. WITH THE Office			
Address for correspondence: Mark this check-box where no agent or common a	epresentative is/has been appointed and the			
space above is used instead to indicate a special address to which correspondence	should be sent.			
Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION				
Statement concerning amendments:*				
1. The applicant wishes the international preliminary examination to start on the basis of	r:			
the international application as originally filed				
the description X as originally filed				
as amended under Article 34	ļ			
the claims as originally filed				
as amended under Article 19 (together with any accompanying	ig statement)			
as amended under Article 34	. Satisfication			
the drawings as originally filed				
as amended under Article 34				
The applicant wishes any amendment to the claims under Article 19 to be consid. Where the IPFA wishes to start the international preliminary examination at the	ered as reversed.			
accordance with Rule 69.1(b), the applicant requests the IPFA to postnone	the start of the international preliminary			
committation with the expiration of the applicable time limit under Rule 69.1(d).				
4. The applicant expressly wishes the international preliminary examination to sapplicable time limit under Rule 54bis.1(a).	start earlier than at the expiration of the			
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* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application				
under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.				
Language for the purposes of international preliminary examination: ENGLISH				
which is the language in which the international application was filed				
which is the language of a translation furnished for the purposes of international search				
which is the language of publication of the international application				
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Box No. V ELECTION OF STATES				
The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the				
PCT.				

International application No. Sheet No. .. 4 PCT/US2004/38044 Box No. VI CHECK LIST The demand is accompanied by the following elements, in the language referred to in For International Preliminary Box No. IV, for the purposes of international preliminary examination: Examining Authority use only not received translation of international application sheets amendments under Article 34 sheets copy (or, where required, translation) of amendments under Article 19 sheets copy (or, where required, translation) of statement under Article 19 sheets 5. letter sheets 6. other (specify) sheets The demand is also accompanied by the item(s) marked below: 1. fee calculation sheet 5. statement explaining lack of signature original separate power of attorney 6. sequence listing in electronic form 3. original general power of attorney tables in electronic form related to a sequence listing copy of general power of attorney; 8. other (specify): RETURN POSTCARD reference number, if any: Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand). For International Preliminary Examining Authority use only 1. Date of actual receipt of DEMAND:

to CORRECTIONS under Rule 60.1(b):				
3.	The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.	6.	The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8, below, does not apply.	
	The applicant has been informed accordingly.	7.	The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of	
4.	The date of receipt of the demand is WITHIN the time limit of 19 months from the priority date as extended by virtue of Rule 80.5.	8. [7]	Rule 80.5. Although the date of receipt of the demand is after the	
5.	Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.	, L	expiration of the time limit under Rule 54bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82.	

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Demand received from IPEA on:

PCT

FEE CALCULATION SHEET

Annex to the Demand

	national cation No.	PCT/US2004/38	044		For International Preliminar	y Examining Authority use only
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Appli	icant					1
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d c	(This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit) Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.		Date: 4 April 2006 Name: J. Herbertt O'Toole Signature: Arrowll Tool			
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Form PCT/IPEA/401 (Annex) (April 2006)

See Notes to the fee calculation sheet

- **10/578957**

BEFORE THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY APPLICATION FILED UNDER THE PATENT COOPERATION TREATY IPEA/US

INTERNATIONAL APPLICATION NO.:

PCT/US2004/038044

INTERNATIONAL FILING DATE:

15 November 2004

APPLICANTS:

DIGITALDERM, INC.

TITLE:

IMAGE MANAGEMENT SYSTEM

FOR USE IN DERMATOLOGICAL

EXAMINATIONS

ATTORNEY REFERENCE:

32483-05

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 ATTN: IPEA/US

VIA EXPRESS MAIL

LETTER TRANSMITTING THE DEMAND FOR INTERNATIONAL PRELIMINARY EXAMINATION UNDER PCT ARTICLE 31 AND REPLY TO WRITTEN OPINION AND ARTICLE 34 AMENDMENT

Dear Sir:

Transmitted herewith for timely filing before the USPTO by the deadline of 13 May 2006 is a completed Demand document under PCT Article 31.

Applicants are also filing their Reply to the Written Opinion dated 13 February 2006, including an Article 34 Amendment consisting of Replacement Sheets 26-28.

Claims 1, 6 and 7 are amended. Claims 2-5 and 8-20 remain unchanged.

REMARKS

Claims 1-4, 6-10, and 13-20 are said to lack an inventive step under PCT Article 33(3) as being obvious over Kenet et al (US 5,291,889) and further in view of Imran et al (US 6,251,073). Applicant respectfully disagrees in view of the amendments to the claims of the present application. In particular, as explained below, Imran et al do not teach the missing element of Kenet et al. Furthermore, Kenet et al is not properly combinable with Imran et al, and there is no motivation to modify Kenet et al in view of Imran et al.

As a preliminary matter, Kenet et al do not disclose plural digital images of the entire skin of the patient, as the office action suggests and supports by its reference to Col. 4, lines 19-24. Kenet does not teach plural images showing the entire skin of the patient stored in

memory but rather only an image of the skin stored in memory. Kenet et al do not teach storage of a complete set of images of the entire skin of the patient.

The office action states that Kenet et al do not teach a software application being carried on a portable memory storage device, but that Imran et al, said to be in the same field of endeavor, do teach that feature, at col. 12, lines 63-67. Applicant respectfully disagrees with both the statement as to the field of endeavor of Imran et al and the statement as to the teachings of the cited passage in Imran et al.

Beginning with this second point first, the cited passage merely teaches that the images on a random access memory card can be removed and inserted into a notebook computer to display the successive kinetic image of the organ being examined. It does not say -- and there is no reason to infer -- that the software for managing these images is on the portable device and in particular downloads with the images. It is perhaps more likely that the software for "playing" the images is a well known application commonly found on the hard drives of notebook computers or downloadable from the Internet, such as Windows Media player. Perhaps even more important, "playing" the images is not the same as managing them, which includes navigating them in a rational order so that each one can be studied in detail, with portions selected and enlarged in a rational order, so that eventually all parts of the skin of the patient can be examined. Managing includes selecting portions of skin for closer examination, allowing the annotation of the selected portions, and displaying images in a spatial sequence and not a temporal one, as Imran et al do. Therefore, Imran et al does not teach the element that is the office action says it teaches. Accordingly, assuming that those of ordinary skill would have been motivated to look to the teachings of Imran et al for a way to modify Kenet et al,, which Applicant asserts they would not, they would not find the missing element and would not therefore be motivated to make the modification postulated by the office action based on Imran et al.

In addition, even assuming that Imran et al *suggests* (which Applicant respectfully submits it does not) that the image-managing software could be carried on the memory device, it would not be at all clear from Imran et al that a device suitable for ultrasonic scanning of internal organs and tissues for tumors would be appropriate to meet the storage requirements for storage of both plural images of the entire skin of the patient and the managing software.

Turning back to the first point raised, namely, the relatedness of the invention of Imran et al to that of Kenet et al., Applicant respectfully submits that the fact that both Kenet et al and Imran et al teach devices for medical diagnostics is not sufficient in and of itself for

a determination of the relatedness of these inventions. Rather, the significant differences in the technology that are employed by these two references to obtain the information needed for their intended diagnoses show them to be unrelated in major and relevant ways. These difference are such that those of ordinary skill would not think to combine the technologies of Imran et al with Kemet et al.

For example, Kenet et al use light (electromagnetic) waves rather than ultrasound (pressure) waves. The importance of this difference is particularly clear when one considers the resolution provided by their respective devices, as well as the impracticability of using light for (non-invasive) examination of internal organs and the pointlessness of using ultrasound for skin examination when skin can be seen and photographed. Kenet et al looks at skin for cancerous lesions; Imran et al look at internal tissues and organs for many things but including the presence of cancerous tumors, for example. Cancerous lesions of the skin may be very small and skin is the largest organ of the body. The internal tissues and organs that are subjected to ultrasonic examination are small compared to skin and the cancerous tumors that may be the focus of the ultrasonic investigation are comparatively large compared to cancerous lesions, or so one hopes. The data requirements of the two for full examination are thus much different. Additionally, Kenet et al is concerned about aligning and presenting a live and a reference image; Imran et al, on the other hand, is concerned with presenting a temporal sequence of live images of the same organ. Thus, in addition to their technologies being unrelated, their objectives are also completely unrelated.

Importantly, then, those of ordinary skill would not necessarily consider the device of Imran et al in looking to improve Kenet et al. And, as noted above, even if they did, there is no basis for concluding that those of ordinary skill would modify Kenet et al in a way that makes Applicants' invention obvious.

Therefore those of ordinary skill in the art of dermatological examination of skin would not find devices for ultrasonic examination of internal organs particularly relevant to meet their requirements for dermatological examinations, or for that matter that the teachings of an ultrasound device can be readily modified for use in dermatological examination.

Finally, there is no motivation in either reference to combine it with the other. The office action states that those of ordinary skill would be motivated to combine the teachings of these two references to store image management software on a portable image storage device. Applicant claims storage of images of the entire skin of the patient for review in a spatial sequence. The motivation recited in the office action is thus inadequate to permit these references to be properly combined. Moreover, the motivation that would be required

to modify Kenet et al in view of Imran et al to make Applicant's device obvious does not come from either reference, even if hindsight were used.

The office action cites col. 3, lines 22-27, in support for the rejection of claim 3, which limits each image to at least 6 million pixels. However, the cited passage does not indicate how many pixels are used in each image. Nowhere in Kenet is there mention of the number of pixels, much less six million, in each image or the number of images.

The office action cites col. 4, lines 28-32, for support for rejecting claim 4, which recites the software application's capability to permit comparison of images. Indeed, Kenet et al compare real time to reference images but they do not teach placing the software they use, unlike Applicant's claimed invention, on the portable memory storage device, and Imran et al does not teach a portable storage device with software carried thereon adapted for *comparing* images, as claimed by applicant, but rather only for producing a kinetic sequence of images. Again, Applicant claims the placing of software for comparing images on the portable memory storage device and neither Kenet et al nor Imran, et al do.

The office action rejects claim 6 in view of Kenet al al, citing several different passages of their specification to support the rejection. For example, the citation to col. 4, lines 25-27, is used to support the rejection of a graphical user interface for the user to view the plural images. The cited passage, however, only indicates that Kenet et al teaches a switch that allows a user to switch between the real and the reference display (i.e., Kenet actually teaches a manual "user interface"). Applicant, on the other hand, teaches and claims a graphical user interface to control a number of aspects of the display of plural images such as order, resolution, brightness, contrast, selection, etc., and not just to switch from one image to another.

Applicant also claims, in claim 6, the ability to adjust magnification of the images. In rejecting this limitation, the office action refers to col. 2, lines 39-43, for support. However, this cited passage does not teach magnification of the image but rather a way of displaying two images at the same time in a "see-through" manner by moving the pixels of one image apart to make room for the pixels of another image. Applicant's magnification of a single image for close up examination is significantly different from the interleaving of the two images being compared by Kenet et al. The advantage of Applicant's magnification is that it allows tiny but suspect moles, for example, to be seen very clearly at more than life size, thus allowing evaluation of their potential as cancerous melanoma at earlier stages in their development. Kenet, et al, are much more interested in only one of the four ABCD factors that are used to evaluate moles, namely, change.

The office action cites col. 2, lines 23-26, in rejecting applicant's claim 6 limitation regarding means for selecting portions of plural digital images for display. The cited passage does indeed say that portions of the reference image may be displayed. However, the selection is not a selection of any area of interest but of applying a masking function to an image (see col. 4, lines 32-38) which limits what the user can see to only what the masking function permits and does not allow the user to select any and every portion of the images for display.

The office action cites col. 2, lines 32-38, of Kenet et al. for support in rejecting the limitation in claim 6 directed to "means for annotating said plural digital images when said plural digital images are stored in said memory." The cited passage (actually col. 4, lines 32-38) indicates that the real time image and the reference image are labeled "one or two." It is clear that the user is not labeling these images, rather, the software is automatically applying the appropriate number the images so the user can tell quickly whether he is looking at a live image or a reference image. Certainly, Kenet et al do not teach annotating the images. In contrast, Applicant's images can be annotated with whatever notations the examining physician chooses, such as "excise immediately." The label in Kenet et al is simply for the examining physician to know which image is the live image and which is the reference image. Applicant's annotation capability is to allow the examining physician to place his or her notes in association with a specific image. There is no provision in Kenet et al for the physician to make notes on the image.

With respect to claim 7, the office action notes that Kenet et al disclose a software application that permits comparison of plural digital images at col. 4, lines 27-32. Indeed, the whole tenor of Kenet is the comparison of two real time and reference images, but not two stored images

With respect to the rejection of claim 13, the office action notes that Kenet et al teaches 33 stored images of 6 million pixels each, supporting that assertion by citing col. 4 lines 19-26. The Attorney for Applicant cannot locate in Kenet et al there or elsewhere such a teaching and requests verification of the citation.

Claim 15 stands rejected because Kenet teaches (at col. 4, lines 28-32) comparison of two sets of stored images. Kenet teaches comparison of a live and a stored, reference image but not two sets of stored images, as claimed by Applicant.

The office action rejects claim 16 because it states that Kenet et al teach (at col. 4, lines 28-32) comparison of two sets of images side by side. To the contrary, Kenet et al do not compare images side-by-side but have much different ways of superimposing and

intermingling images to produce a composite image. See Kemet's abstract; see col. 2, lines 21-44 in the Summary of the Invention; and the entire Disclosure of Preferred Embodiment.

The office action rejects claim 18, in view of cited teachings in Kenet et al that purport to teach that photographs are taken normal to the skin of the patient. The citations to col. 3, lines 30-39 do not appear to contain this teaching. Attorney for Applicant is unable to locate any guidance or teaching in Kenet et al with respect to how the photographs are to be taken.

The office action rejects claim 20, in view of the cited teachings of Kenet et al that purport to teach, at col. 4, lines 19-27, the step of installing a software application on the digital memory device for managing the first set of plural digital images. Rather, the cited passage discloses storing images in a digital memory but not also the software for managing them. Thus, the cited passages do not appear to teach the limitation of claim 20.

The office action states that claims 5, 11, and 12 are obvious over Kenet et al, Imran et al, and Killcommons et al. This rejection is respectfully traversed in view of the remarks made above with respect to Kenet et al and Imran et al and the amendments to the claims.

Killcommons et al address the transfer of information over a network, such as medical information. The office action cites col. 13, lines 64-67, to support the rejection of a claim limitation directed to magnification up to 3200%. The cited passage describes magnification up to 600%. While the cited passage clearly shows that magnifying images is known, it does not suggest magnification up to 3200% or even close to that. It in fact teaches away from that level of magnification by reciting an upper limit of only 600%. It is important to point out that the same passage that limits magnification to 600% is in the context of ultrasonic images where greater magnification may not have any value because of limited resolution. In dermatological examination, however, very small moles may be the subject of interest and may need to be magnified large enough to see their details. Finally, throughout Kilcommons, the data acquired is all digital with inherent limited ability to enlarge the images. Applicant's images are photographs that are then digitized in the requisite number of pixels per image (six million) that will permit magnification to 3200%. Accordingly, those of ordinary skill would not find motivation from Kilcommons (or Kenet et al or Imran et al) to provide magnification up to 3200%.

Claim 12 is rejected based on the teachings of Killcommons with respect to the capability of showing the images in reverse (col. 13, lines 56-59). Killcommons does not teach reversing the images but only showing a sequence of images in reverse *order*. The images, shown in regular order or reverse order, are not reversed images. Applicant provides

an image reversing procedure so that a patient can examine his or her back, for example, and compare the images (reversed) with what he or she sees in a mirror. This feature is not taught or suggested by Killcommons and is not obvious in view of them.

CONCLUSION

In view of the foregoing remarks and attending amendments, Applicants respectfully request the establishment of a favorable International Preliminary Report on Patentability.

Respectfully submitted, NEXSEN PRUET, LLC

J Herbert O'Toole

Attorney/Agent for Applicants

Date 04 April 2006.

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WHAT IS CLAIMED IS:

1. A device for dermoscopic examination of moles on a patient's skin, said device comprising:

a portable memory storage device;

plural digital images showing the entire skin of a patient; and

a software application adapted for managing said plural digital images by facilitating viewing said plural digital images in a range of resolutions and in a special sequence, said plural digital images and said software application being carried on said portable memory storage device.

- 2. The device as recited in claim 1, wherein said portable memory storage device is a compact disk.
- 3. The device as recited in claim 1, wherein said each digital image has at least six million pixels.
- 4. The device as recited in claim 1, wherein said plural digital images include plural sets of digital images, each set of said plural sets of digital images showing the skin of said patient, and wherein said software application is further adapted to permit comparison of said plural sets of digital images so that a user can look for changes over time in moles present on the skin.
 - 5. The device as recited in claim 1, wherein said range of magnification is up to 3200%.
- 6. A system for dermatological examination of moles on a patient's skin, said system comprising:

a memory adapted to store plural digital images showing the skin of a patient; and a software application in communication with said memory and adapted to retrieve digital images from said plural digital images when said plural digital images are stored in said memory, said software application having

a graphical user interface that enables a user to view said plural digital images, means for displaying said plural digital images in a range of magnifications, means for permitting the user to select portions of interest of said plural digital images for display and examination, and

means for annotating said plural digital images when said plural digital images are stored in said memory.

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- 7. The system as recited in claim 6, wherein said software application permits comparison of images of said stored plural digital images.
- 8. The system as recited in claim 7, wherein said software application is adapted to receive annotations to images of said plural digital image.
- 9. The system as recited in claim 8, wherein said software application is adapted to display said plural digital images with annotations.
- 10. The system as recited in claim 6, wherein said software application includes means for acquiring additional digital images and adding said additional images to said memory.
- 11. The system as recited in claim 6, wherein said software application includes meansfor encrypting said plural digital images.
 - 12. The system as recited in claim 6, further comprising means for reversing said plural digital images so that a user can see said plural digital images as if in a mirror.
 - 13. The system as recited in claim 6, wherein said memory is dimensioned to hold at least one set of 33 digital images, each image of said 33 images containing at least six million pixels.
 - 14. A method for dermoscopic examination of moles of a patient's skin, said method comprising the steps of:

making a first set of plural digital images of the skin of a patient; storing said first set of plural digital images in a digital memory device; reviewing said first set of plural digital images in sequence; and annotating said first set of plural digital images.

- 15. The method as recited in claim 14, further comprising the steps of:
 making a second set of plural digital images of the skin of said patient, images of said
 second set corresponding to images of said second set to define image pairs;
- storing said second set of plural digital images in said digital memory device; and comparing said first set to said second set of digital images to determine if there are changes in moles present on the skin of said patient.
- 16. The method as recited in claim 15, wherein said comparing step further comprises the step of comparing image pairs side by side.

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- 17. The method as recited in claim 15, wherein said comparing step further comprises the step of comparing corresponding image pairs by overlaying said images of said first set with images of said second set.
- 18. The method as recited in claim 14, wherein said making step further comprising the step of making each digital image substantially normal to the skin of said patient.
- 19. The method as recited in claim 14, wherein said making step further comprising the step of making each digital image of at least six million pixels.
- 20. The method as recited in claim 14, further comprising the step of installing a software application on said digital memory device, said software application having a graphical user interface and being adapted for managing said first set of plural digital images.